REMARKS

The Office Action mailed June 15, 2007 has been received and reviewed. All pending claims stand rejected. Reconsideration is respectfully requested.

1. Personal Interview:

Applicants thank the Examiner for the courtesy extended applicants' representatives during the interview conducted on October 3, 2007. Applicants appreciate the Examiners' helpful comments. As set forth in the Examiner's Interview Summary, all pending claims were discussed as were the '661 and '831 references. Further, "102 rejections [were] discussed on inherency + 112 (new matter) rejection would be withdrawn". Applicants believe that this description, taken together with this Response, adequately sets forth the substance of the interview. *M.P.E.P. § 713.04.* If the Office determines, however, that further comments are necessary or helpful, the Office is kindly requested to contact applicants' undersigned attorney who will promptly provide any further detail desired.

2. Claim Rejections and 35 U.S.C. § 112

As discussed at the interview, and noted in the Examiner's Interview Summary, the "new matter" rejection of claims 1, 3-8, and 10-14 under 35 U.S.C. § 112 has been withdrawn.

3. Claims Rejections and 35 U.S.C. § 102

Claims 1, 3-7 and 10-14 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 01/72831 as evidenced by Merck Index, Dwinnell *et al.*, Agrawal et al., and Medline Plus Article. Applicants respectfully traverse the rejection.

Regarding claim 1, applicants respectfully submit that it is irrelevant whether the LQGV or AQGV disclosed in WO 01/72831 would inherently reduce BUN concentration. Claim 1 is directed to a method of treating acute renal failure. The claimed method is a novel use of AQGV and other oligopeptides; not a composition claim. A novel use may be patentable. See, for example, M.P.E.P. § 2112.02 wherein it is specifically stated that:

> "[t]he discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using."

WO 01/72831 discloses, *inter alia*, that oligopeptides AQGV and LQGV have an anti-shock effect. *See Table 2, page 61.* The experiments with AQGV and LQGV would not necessarily have resulted in treatment of acute renal failure. WO 01/72831 does not mention acute renal failure. Therefore, claim 1 is novel.

Applicants further submit that WO 01/72831 does not inherently disclose a method of treating acute renal failure. With respect to inherency, M.P.E.P. § 2112 provides:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. *In re Rijckaert,* 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) . . . 'To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'' *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1991).

Septic shock may cause acute renal failure in some cases. As applicants believe was acknowledged at the interview, it occurs at most about half of the time. (*See, e.g.*, eMedicine-"Septic Shock" by Sat Sharma, www.emedicine.com/MED/topeic2101.html, p. 23, copy enclosed, describing that "Acute renal failure occurs in 40-50% of patients with septic shock.") The Office has not established (and can not, because it is not the case) that every case of septic shock will necessarily cause acute renal failure. On the contrary, the Office has only asserted that the Merck Index teaches that a major cause of renal failure is septic shock. *Office Action, p. 3.* The Merck Index at page 1842 lists septicemia as one of 34 "major" causes of acute renal failure. The Merck Index does not disclose that acute renal failure necessarily follows septic shock in every case. Thus, it does not establish that every case (or even a majority of cases) of septic shock result in acute renal failure. Additionally, on page 3, WO 01/72831 provides a definition of septic shock - "[w]hen this syndrome results in hypotension or multiple organ system failure (MOSF), the condition is called sepsis or septic shock." Although it is possible that the kidneys could be one of the organs to fail, clearly numerous other organs could fail without the kidneys failing (*e.g.*, the heart). Tellingly, WO 01/72831 discloses experiments related to the heart and

the spleen, and not related to the kidneys. *See, e.g., pages 65-67.* The Office has not established that septic shock will necessarily cause acute renal failure in every case. Thus, the Office has not established that WO 01/72831 inherently discloses a method of treating acute renal failure. Therefore, claim 1 is novel, and claims 3-7 and 10-14 are novel for at least the reason of depending from novel claim 1.

Dwinnell et al. and Agrawal do not remedy this shortcoming, and the claims are not inherently anticipated.

Additionally regarding claims 12 and 13, applicants respectfully submit that extrinsic evidence has been improperly used in making the 35 U.S.C. § 102 rejections. M.P.E.P. § 2131.01(III) provides that extrinsic "evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." The evidence from the Merck Index does not make clear that the subjects' kidneys in WO 01/72831 were not producing more than ½ ml of urine per hour per kilogram of body mass of the subject. Likewise, the evidence from the Merck Index does not make clear that the subjects in WO 01/72831 had a serum potassium level greater than 6.5 mmol per liter serum. The Merck Index does not relate to the specific experiments of WO 01/72831. Therefore, the Merck Index cannot constitute extrinsic evidence under 35 U.S.C. § 102 for the experiments of WO 01/72831. Therefore, for this additional reason, claims 12 and 13 are not anticipated.

Applicants respectfully request withdrawal of these 35 U.S.C. § 102 rejections.

Claims 1, 3-5, 7, 8, and 10-14 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by US 2004/0013661 as evidenced by Merck Index, Merriam Webster's Dictionary (p. 82), Dwinnell *et al.*, Agrawal et al., and the Medline Plus Article.

Specifically, it was thought that reducing blood urea nitrogen ("BUN") concentration is an inherent property of the oligopeptide composition consisting of SEQ ID NO:2. *Office Action, p. 4.*

Regarding claim 1, applicants respectfully submit that under 35 U.S.C. § 102(e), it is irrelevant whether the LQGV or AQGV disclosed in US 2004/0013661 would inherently reduce BUN concentration if administered to a subject. Claim 1 is directed to a method of treating acute

renal failure. The claimed method is a novel use of AQGV and other oligopeptides. US 2004/0013661 discloses, *inter alia*, that oligopeptides AQGV and LQGV may be used for treatment of sepsis/SIRS. *See paragraph [0041].* However, it is impossible that the experiments in US 2004/0013661 inherently reduced BUN concentration of a subject or treated acute renal failure. The experiments in US 2004/0013661 relate to, *inter alia*, synthesis of gene-regulatory peptides and the testing of gene-regulatory peptides in cells. *See paragraphs [0049] to [0057].* It is impossible for the cells in the experiments to undergo acute renal failure as the cells do not have kidneys or blood. Therefore, it is impossible that those experiments would necessarily have resulted in treatment of acute renal failure or reduced the BUN concentration of a subject. Additionally, US 2004/0013661 does not mention BUN concentration or acute renal failure. Therefore, US 2004/0013661 does not inherently anticipate claim 1. Claims 3-5, 7, 8, and 10-13 are novel for at least the reason of depending from novel claim 1.

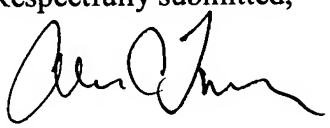
Dwinnell et al. and Agrawal do not remedy this shortcoming, and the claims are not anticipated.

Additionally regarding claims 12 and 13, applicants respectfully submit that extrinsic evidence has been improperly used in making the 35 U.S.C. § 102 rejections. The experiments in US 2004/0013661 do not involve administering AQGV or LQGV to subjects with kidneys. Therefore, it is impossible for the evidence in the Merck Index to make clear that a subject's kidneys in US 2004/0013661 were not producing more than ½ ml of urine per hour per kilogram of body mass of the subject. Likewise, it is impossible for the evidence in the Merck Index to make clear that subjects in US 2004/0013661 had a serum potassium level greater than 6.5 mmol per liter serum. Additionally, the Merck Index does not discuss the specific experiments of US 2004/0013661. Therefore, the Merck Index cannot constitute extrinsic evidence under 35 U.S.C. § 102 for the experiments of US 2004/0013661. Thus, for this additional reason, claims 12 and 13 are not anticipated.

Applicants respectfully request withdrawal of the 35 U.S.C. § 102 rejections.

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Enclosure: Information Disclosure Statement citing eMedicine- "Septic Shock" by Sat Sharma, www.emedicine.com/MED/topeic2101.html